

K122023

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Attachment 5

OCT 4 2012

510(k) Summary

1. Submitter Information

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West Pharmaceutical Services, Inc.
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Lionville, PA 19341
Telephone Number: (610) 594-3105
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Email: debbie.thomas@westpharma.com

Date Prepared: 05 July 2012

2. Device Name

Device Trade Name: Mixject™ with Spray Head
Common Name: Mixject with Spray Head
Classification name: Syringe, Piston

3. Classification

Product Code: FMF
Regulation No.: 880.5860
Class: II
Panel identification: General Hospital Panel

4. Predicate Devices

Predicate 1: Mixject Dispensing Pin with Detachable Vial Holder
(K963583)
Predicate 2: Mixject Dispensing Pin with Detachable Vial Holder
(K001293)
Predicate 3: Laryngo-Tracheal Mucosal Atomization Device
(MADGIC), (K002255)

5. Device description

The Medimop Mixject with Spray Head device enables injection of a diluent into a drug vial connected to the Dispensing pin (Vial adapter), for reconstitution and aspiration of the reconstituted drug into a syringe attached to the luer-lock end of the body. The vial and the Dispensing pin (Vial adapter) can be removed by turning the Dispensing pin (Vial adapter). The removal of the Dispensing pin (Vial adapter) turns the turning core from the aspiration position to the fixed spray position allowing spray application / delivery of the drug onto the desired surface.

6. Indications for use

Transfer, mixing and topical spray application / delivery of drugs with a viscosity up to 4.7cP contained in vials

7. Technological Characteristics and Substantial Equivalence

The Mixject with Spray Head and has the same principle of operation as the predicate devices Mixject Dispensing Pin with Detachable Vial Holder (K963583) and (K001293) and the Laryngo-Tracheal mucosal Atomization Device (MADGIC) (K002255), described as the predicate devices and is therefore substantially equivalent to this devices.

8. Nonclinical Testing

Bench testing was performed to demonstrate the ability of the proposed Mixject with Spray Head to effectively transfer, mix and application of drugs contained in vials.

9. Conclusion

Comparative analysis of technological characteristics between proposed and predicate devices and results of verification testing performed demonstrate that the subject device is substantially equivalent to the legally marketed predicate devices. Any differences between the proposed and predicate devices do not raise any additional concerns regarding safety and effectiveness and may therefore be considered substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Medimop Medical Projects, Limited
C/O Ms. Deborah M. Thomas
West Pharmaceutical Services, Incorporated
101 Gordon Drive
Lionville, Pennsylvania 19341

OCT 4 2012

Re: K122023
Trade/Device Name: Mixject™ with Spray Head
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: July 9, 2012
Received: July 11, 2012

Dear Ms. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

For 

Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Mixject with Spray Head

Indications for Use:

Transfer, mixing and topical spray application / delivery of drugs with a viscosity up to 4.7cP contained in vials

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Rehab C Chyn 10/4/12
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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